Lauri Kuosmanen

TRIPS and Pharmaceutical Patents:

Effects on Access to Essential Medicine and Innovation

Helsinki Metropolia University of Applied Sciences

Bachelor of Business Administration

European Management

Thesis

6 May 2016

Helsinki Metropolia University of Applied Sciences

Author(s) Title Number of Pages Date	Lauri Kuosmanen TRIPS and Pharmaceutical Patents: Effects on Access to Essential Medicine and Innovation 35 pages + 1 appendix 6 May 2016
Degree	Bachelor of Business Administration
Degree Programme	European Management
Specialisation option	N/A
Instructor(s)	Rosli Kamarul-Baharin, Senior Lecturer

The purpose of this thesis is to examine how intellectual property rights and patent protection affect access to essential medicine and innovation. The focal point of this thesis is the Agreement on Trade-Related Aspects of Intellectual Property Rights, which has been implemented by all WTO members, thus covering most of international trade. This thesis mainly focuses on developing countries in need of essential medicine, as the potential restricting effects are the most drastic in these countries.

The public debate surrounding the TRIPS agreement has repeatedly brought up two contrasting notions. On one hand, patent protection is seen as restricting access to essential medicine, whereas on the other hand, it is seen as necessary to encourage research and development. Thus, this thesis focuses on a comparative analysis of these two contrasting notions in an effort to identify what could be done to ensure access to essential medicine without undermining future innovation.

The study relies on a qualitative analysis of secondary literary sources, including publications by the WTO, pertinent NGOs and the pharmaceutical industry. Existing quantitative analyses were also used to examine the relationship between patent protection and innovation.

This study finds that patent protection and the TRIPS agreement restrict access to essential medicine. Patent protection in itself is also unlikely to lead to the build-up of innovative capacities in developing countries. Furthermore, patent protection is unlikely to encourage the development of products that cater to markets, such as developing countries, which are unable to pay the high prices required to recoup the costs of research and development.

The study concludes that the TRIPS agreement could be amended to facilitate easier access to medicine in public health crises, while taking into account the commercial interests of the patent holder. Working within a TRIPS-system would also require increased public spending and charitable efforts to develop products that cater to developing countries. The effects of patent protection on innovation in the public sector is also identified as a topic of further studies.

Keywords	intellectual property rights, patents, TRIPS, essential medicine, pharmaceutical products

Contents

1 Introduction

The Uruguay Round of multilateral trade negotiations between 1986 and 1994 saw the formation of two major factors to international trade, namely the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The latter is an agreement signed by all WTO member states, which established the minimum level of intellectual property protection (IPR) to be implemented in all member states. As intellectual property had become an important part of trade, which itself had become increasingly international, TRIPS was negotiated to establish common standards of IPR in order to provide order and predictability to international trade.

Following the entry into force of TRIPS, trade disputes and public debate ensued on the topic of access to medicine. While the major trade disputes were settled relatively quickly, the public debate has remained to this day. Developing countries have been hit hardest by disease, the region of Sub-Saharan Africa carrying arguably the heaviest burden of disease. Despite efforts being made to ensure access to medicine, it continues to be a major obstacle to treating epidemics of AIDS, Malaria and Tuberculosis.

1.1 Objective and Scope

The objective of this thesis is to examine the effects of TRIPS and patent protection on access to medicine. It is important to firstly gain an understanding of how patent protection affects access to medicine, and then to identify what could be done to facilitate easier access in areas of need. The effects of TRIPS on access to medicine are discussed through two prominent trade disputes that followed the implementation of TRIPS. The cases of the Brazilian and South African healthcare reforms in the 1990's, and the consequent trade disputes, have helped to identify outstanding issues in the access debate. These two disputes and the motivations of the parties involved bring up the dilemma of patent protection restricting access to medicine, while also acting as a means to encourage innovation. The two main questions this thesis aims to answer are (1) does TRIPS restrict access to medicine and (2) whether this is necessary to encourage research and development (R&D). Through a comparative analysis of these

two conflicting notions, this thesis aims to identify what could be done to ensure access to essential medicine without risking a drop in R&D efforts.

While the necessity of IPR in general has been the subject of debate, this thesis will focus on the pharmaceutical industry and pharmaceutical products for two reasons. Firstly, the R&D process in pharmaceuticals differs radically from other industries. Secondly, pharmaceutical products, and especially essential medicine, differ radically from other goods, e.g. computers or smart phones, due to their paramount importance in public health. The countries of focus of this thesis could be rather loosely considered to be developing countries dealing with public health crises and a need for access to essential medicines. While the most prominent proportion of such countries, and the largest burden of disease, is located in Sub-Saharan Africa, Brazil is also included in this group of target countries for the purposes of this thesis due to their public health crises, healthcare reform, and prominent role in the access debate.

1.2 Method and Limitations

This relies on a qualitative analysis of secondary literary sources. Due to the nature of this paper being a commentary and participation in the debate regarding access to essential medicine, all sides of the debate – the WTO, NGOs and the pharmaceutical industry – are used as sources for their respective sides on the debate. Further literary sources in the forms of relevant books and peer-reviewed journal articles are used to firstly fill gaps in information, and secondly to support the author's own argumentation.

It must be acknowledged that due to the nature of the topic, the participants of the debate are likely to have their own agendas to push. Thus, whenever deemed necessary and proven possible, the facts and figures cited by the various organisations featured in this paper have been verified from as many sources as possible, in order to ensure the objectivity of this paper.

This paper also cites quantitative analyses of the relationship between patent protection and innovation. While the studies are based on a large data set to ensure reliability, it must be noted that these studies were done across all industries. Due to the drastically different cost structure – mainly the importance of substantial up-front costs of new product development – of the pharmaceutical industry, the findings of the cited studies should be considered tentatively. More limited studies on the effects of patent

protection on R&D specifically within individual national pharmaceutical industries do exist, but the timeframe of these studies is relatively limited due to the fact that patent protection on pharmaceutical products has been a recent development in many countries.

During the research process, it proved to be very difficult to gain insight into the effects of patent protection on publicly funded pharmaceutical R&D. The universities and research laboratories operating on public funding are also applying for patents on their inventions, but it remains inconclusive to which degree their R&D efforts are guided by the financial gains associated with patents and licensing agreements. This relationship between patent protection and R&D in the public sector is identified as an area of further research.

2 Background and Key Definitions

2.1 The Access Problem

Roughly 70 percent of the total people living with HIV reside in Africa, despite it representing only 15 percent of the global total population. Sub-Saharan Africa is most affected by the epidemic with nearly all of the HIV-infected population of Africa (UNAIDS, 2013). The area is home to roughly 25 million HIV-infected people, and the rate of new infections has hovered around the 1.5 million mark in recent years. Estimated AIDS-related deaths in the area in 2014 totalled at 790 000, down from the annual average of 1.2 million between 2000 and 2012 (UNAIDS, 2015). While strides have been taken in forcing the amount of new infections to a decline, and matching the numbers of access to treatment with the new infections, the public health issues are far from solved.

While HIV tends to receive the most publicity and have the highest shock value, it is not the only public health concern in the area. Tuberculosis is another serious risk to public health occurring mainly in low- and middle-income countries. In recent years, it has even surpassed AIDS as the infectious disease accounting for most deaths worldwide. It is also a leading cause of death among HIV-positive people, accounting for roughly a third of HIV-related deaths. While over half of new infections occur in South-East Asia and the Western Pacific, Africa has the most infections per capita (WHO, 2016a).

Malaria is another life-threatening disease mostly prevalent in Sub-Saharan Africa. Young children and pregnant women are particularly susceptible to it. While it is both preventable and curable, it poses a significant health risk to a relatively focused region. Sub-Saharan Africa is clearly the most affected, representing roughly 90 percent of the over 200 million cases and nearly 500,000 deaths reported globally in 2015 (WHO, 2016b).

Developing countries and Least Developed Countries (LDCs) have been hit hardest by disease; out of the 30 countries classified as LDCs, 25 are located in Sub-Saharan Africa. Various socioeconomic factors present challenges to effective prevention and

treatment of disease in this region. It is home to substantial, oft-neglected rural populations that are often dealing with poor infrastructure and a lack of basic necessities. Essentials such as clean water and basic sanitation are often scarce, which is a major factor in the spreading of disease. Furthermore, the isolation and poor infrastructure present their own difficulties to accessing healthcare. And even the healthcare systems themselves are often dealing with their own issues, such as a lack of qualified personnel, limited resources and poor infrastructure. In addition, unstable political conditions and corruption present obstacles on yet another facet of society (CIA, n.d.). While the access problem obviously has several facets – the price of drugs being merely one of them – the commentary in the following sections will deal mostly with the contribution of IPR protection on the phenomenon known as the access problem.

2.2 Pharmaceutical Products and Essential Medicine

For the purposes of this thesis, the term pharmaceutical product refers to drugs that are used to prevent, diagnose, treat and cure disease. This definition includes both synthetic drugs such as Aspirin as well as biopharmaceutical products such as antibiotics and vaccines.

The World Health Organization (WHO) publishes a biannual list of essential medicines. These are the drugs that satisfy the priority health care needs of the population, and they should ideally be available in adequate quality and quantities, correct dosage forms, and at prices that are affordable to the population. The list is not a global standard *per se*, as most countries publish their own national lists. However, it has become a common concept in promoting health equity (WHO, 2016d). The products on the list range from basic necessities such as painkillers, antibiotics and vaccines to more complex treatments for life threatening disease such as AIDS and multidrug-resistant tuberculosis. As the list is updated biannually with the addition of new drugs considered essential, some of which are under patent protection and thus relatively expensive, this group of pharmaceuticals has become something of a focal point in the access debate.

2.3 The TRIPS Agreement

The Uruguay Round of multilateral trade negotiations, conducted within the framework of the General Agreement on Tariffs and Trade (GATT), took place between 1986 and 1994. The negotiations dragged on for nearly twice the originally intended schedule, and the topics discussed covered nearly all aspects of international trade. At completion in April 1994, the then 123 member states came to an agreement. As a result, the WTO was created, and it took over as the successor to GATT on January 1st, 1995. While GATT was replaced, it still serves as the foundations of the WTO (WTO, 2014a).

The TRIPS Agreement was also negotiated during the Uruguay Round. Similar to the trade negotiations and the WTO, the negotiations on intellectual property rights were vast in scope and built upon already existing agreements, such as the Berne, Paris and Rome Conventions. Unlike GATT and WTO, TRIPS did not replace these conventions, but rather acknowledged and reiterated overlapping parts of them (WTO, 1994). Considering the constant and rapid technological development at the time, many industries had become increasingly dependent on innovation, research and testing. And as trade was becoming increasingly international, and intellectual property had gained importance as a source of wealth – at least in developed, industrialised countries – the establishment of common rules was perceived important. The TRIPS Agreement was negotiated with the aim of narrowing gaps in how IPRs were protected in member states, in order to facilitate stability and predictability in trade. It aimed to do so by establishing common minimum standards of IPR protection for all member states (WTO, 2014b).

Member states were given a one-year transition period for implementing the TRIPS Agreement. In order to aid the less developed member states in their transition to TRIPS-compliance, two types of extensions were given. Developing countries and countries under-taking structural reforms were given a four-year extension, whereas the 20 member states classified as LDCs received a ten-year extension. In an effort to mitigate possible adverse effects of implementing the agreement – for example limited access to medicine during public health crises – the agreement provided two mechanisms: compulsory licensing and parallel imports (WTO, 1994).

2.4 Patent Protection as Applied under TRIPS

Under TRIPS, member states are obliged to grant patent protection to any invention – whether product or process – in all fields of technology. Patentable subject matter must firstly be new, meaning that it cannot be already considered public domain or be considered common technical knowledge in the field in question. Secondly, the invention must consider an inventive step, meaning that it cannot be deducted by using common technical knowledge. Lastly, the invention must be capable of industrial application. Patents are to be available without discrimination as to the place of invention or whether it is imported or locally produced. The minimum patent duration is 20 years from the date of filing of the patent application.

Patents on new products prevent third parties from making, using, offering for sale, and selling or importing for these purposes of the product, without the consent of the patent owner. Patents on new processes, on the other hand, prevent third parties from using, offering for sale, and selling or importing for these purposes of the product obtained through the patented process, without the consent of the patent owner. Patent owners are free to transfer the patent or to conclude licensing agreements for third parties to the patent at their discretion.

TRIPS Article 31 allows for compulsory licenses to be issued under certain conditions in case it is in line with the legislation of the member state. Compulsory licensing allows for the use of the patented subject matter by the government or third parties authorised by the government without the consent of the patent owner. The most fundamental requirement is that the proposed user of the license must have made efforts to obtain a license under reasonable commercial terms, and that this has not been successful within a reasonable amount of time. This requirement may be waived, however, in the case of a national emergency or in other circumstances of extreme urgency. In such cases, the patent owner must simply be notified as soon as possible that a compulsory license will be or has been issued. Such compulsory licenses must be non-exclusive and used mainly for the supply of the domestic market. In case a compulsory license is issued, the patent owner is to be paid adequate remuneration depending on the economic value of the compulsory license.

As this paper discusses TRIPS in the context of pharmaceutical products, it is worth noting that this provision would allow for governments to issue a compulsory license in order to drive down the price of a drug by introducing generic competition to the market. The manufacturer of a generic drug would be able to manufacture and sell the product at a significantly lower cost and price, as they would avoid the high costs associated with research, development and clinical testing already incurred by the patent owner.

Another flexibility provided by TRIPS is the use of parallel imports. Article 6 states that none of the provisions of the agreement may be used to address the issue of exhaustion of IPR, unless it is in cases of non-discrimination. In other words, each member state has the discretion to decide the point at which IPRs become exhausted by themselves. After the IPRs have become exhausted, it is possible to engage in parallel importing.

This flexibility relies on the concept that the patent owner holds no rights over the patented product once it has been sold at their consent at a market. For example, if the patent owner or another party with the permission of the patent owner has sold a product in Country A, and it is then imported by the purchaser to be sold in Country B, it is known as a parallel import. In practice, this would make it possible to source the lowest global price in an effort to combat differential pricing. For example, if a drug is patented in both Country A and Country B, but sold at a lower price in Country A, it would be possible to purchase the drug in Country A and then import it to Country B to be sold at a price lower than before.

TRIPS entered into force on 1 January 1995 with a one-year transition period, meaning that the national laws of member states had to meet all of the aforementioned minimum requirements by 1 January 1996. Two types of extensions to the general transition period were given. Developing countries and countries undertaking structural reforms were given a four-year extension, requiring TRIPS-compliance by 1 January 2000. The then 20 countries classified as LDCs were received a ten-year extension, requiring TRIPS compliance by 1 January 2006. An additional five-year extension was also given to developing countries for applying patent protection to areas of technology that did not have patent protection prior to TRIPS. Thus, if a developing country did

not grant patent protection to pharmaceutical products prior to the entry into force of TRIPS, they had until 1 January 2005 to apply patent protection.

Despite the extensions given, each member state was required to begin to accept patent applications for new inventions beginning from 1 January 1995. In case a patent application was filed prior to a national patent law having been passed, the application would be examined after the relevant patent law was passed taking into account the prior art of the time of the initial patent application. In case of a successful application, patent protection would be applied to the remaining patent duration counted from the date of the initial application. Under TRIPS, patents would only apply to new inventions, and any product patented elsewhere prior to 1 January 1995 would not be required to be granted patent protection.

Brazil and South Africa – the two countries highlighted in this thesis – became TRIPS-compliant with pharmaceutical patents in 1996 and 1997, respectively. India – another country noted for their extensive production of generic pharmaceuticals – made use of all the possible flexibilities and became TRIPS-compliant with pharmaceuticals on 1 January 2005.

2.5 Evolution of the Agreement

2.5.1 The Doha Declaration on the TRIPS Agreement and Public Health

The 4th WTO Ministerial Conference was held in Doha, Qatar in November 2001. Leading up to the conference, the African member states had taken a unified stance and a cohesive agenda in pointing out their special needs in regard to access to medicine ('t Hoen, 2002: 50). In response to this and the public debate that had followed the TRIPS Agreement, the WTO made an important declaration in Doha. The declaration recognised the gravity of the public health concerns in developing countries and LDCs, and acknowledged the importance of TRIPS in overcoming these issues. Thus, the WTO stressed that TRIPS could and should be implemented by the member states in a way that promoted public health and access to medicine for all (WTO, 2001).

The declaration also stressed several times that member states were allowed to act autonomously in setting their legislation. This could be seen as touching upon the potential problem of developing countries and LDCs being pressured into setting patent laws that are more restrictive than required by TRIPS (WTO, 2001). The legal action of Pharmaceutical Manufacturers' Association against South Africa, and the related trade sanctions imposed by the United States – which will be discussed in their own chapter in more detail – were a prime example of this. While the statement might have seemed somewhat superfluous, it could have also been seen as a first step towards building consensus.

Most importantly, certain key technicalities of TRIPS were also clarified. In regard to parallel imports, the content of the agreement was simply reiterated – each member state was free to determine the point at which IPR became exhausted, and that such decisions could not be challenged on any other grounds than non-discrimination. As already mentioned in section 2.4, the concept of exhaustion is what enabled member states to engage in parallel imports. On the topic of compulsory licensing, it was stated that each member had the right to grant compulsory licenses, and – most importantly – each member was free to determine the grounds on which they were granted, and what constituted as a "national emergency" or "other circumstances of extreme urgency" (WTO, 2001).

The then 29 member states that were classified as LDCs were also given a further extension on implementing the parts of TRIPS - related to patent protection and protection of undisclosed information – in the context of pharmaceutical products. This meant that the LDCs had until 1 January 2016 to consider at least parts of their future IPR legislation (WTO, 2001).

One of the few major questions that remained unanswered after the declaration was related to TRIPS Article 31(f), which limited the use of compulsory licensing predominantly for the domestic market of the member states. This issue could prove to be particularly problematic for those member states with little to no manufacturing capacity, as well as those with the capacity and willingness to help other member states. However, the declaration did acknowledge the issue, and its potential to limiting some member states' effective use of the flexibilities provided by TRIPS. It called for the

TRIPS Council to find a prompt solution to the issue, latest by the end of 2002 (WTO, 2001). This part of the declaration became to be known as the Doha Assignment.

2.5.2 The Doha Assignment

The completion of the Doha Assignment was delayed by nearly a year, but finally, in September 2003, a decision was finally made on TRIPS Article 31(f) and the outstanding issue of exporting under a compulsory license. One of the major reasons for the delay was the fear that a solution not specific enough could potentially lead to unforeseen effects – such as application in too wide a scope – in the domestic markets of developed member states (Barton, 2004: 149). Finally, the solution was limited to be used in good faith, and to only apply to pharmaceutical products in order to protect public health. It was also stressed that the risk of trade diversion – i.e. re-exportation of the products to markets other than the specific importer – should be mitigated (WTO, 2003).

With this solution, any member state with insufficient manufacturing capacity could issue a compulsory license and import a generic version of a drug to address public health concerns within their borders. The terms for this process were quite straightforward. Initially, the importing member state is required to notify the TRIPS Council of its intent to use the system, provide sufficient proof of the lack of manufacturing capacity, and to specify the names and quantities of the drugs imported before issuing a compulsory license. The exporting country, in turn, is required to notify the TRIPS Council of its intent to export, produce only the exact amounts required, and to differentiate the exported products from any other versions of the product they might manufacture (WTO, 2003).

2.5.3 Amendment of the Agreement

The TRIPS Agreement was amended to its current form in December 2005, with the addition of content similar to the aforementioned Doha Assignment. The solution to issues related to Article 31(f) was already presented in September 2003, and finally annexed to TRIPS as Article 31bis. The mechanism that enabled the export of products

manufactured under a compulsory license remained unchanged from the one presented in 2003 (WTO, 2005).

Article 31bis(3) also technically enables member states to act together in order to benefit from economies of scale in manufacturing or importing pharmaceutical products manufactured under a compulsory license, and then exporting it to the other member states. This article applies to developing countries and LDCs under three specific conditions. Firstly, the member states must all be members of the same regional trade agreement and share the same public health concern. Secondly, at least half of the members of the regional trade agreement must be LDCs. And thirdly, one single member state must handle all of the administration, import and distribution on behalf of the participating members (WTO, 2005).

While the system might be criticised for adding unnecessary administrative hurdles to the process, it must at least be acknowledged that it does provide relatively good coverage of the African continent. All of Sub-Saharan Africa, with the exception of six states – Eritrea, Ethiopia, Djibouti, Mauritania, Somalia and Sudan – are members of eligible regional trade agreements. It should further be noted that of the 25 LDCs on the African continent, only two – Mauritania and Djibouti – are not benefitting from the flexibilities of this mechanism. Thus, the countries dealing with the worst public health crises are at least included (WTO, 2016).

2.6 TRIPS-Plus Provisions

The TRIPS Agreement sets only a minimum standard of IPR protection for all member states. Any provisions that go beyond those of TRIPS are commonly referred to as TRIPS-plus provisions. Such provisions are frequently found in bilateral or regional free trade agreements, for example in roughly 60 agreements in which the United States has been a negotiating party (Cohen-Kohler, Forman & Lipkus, 2008: 241). Considering the vast amount of free trade agreements currently in place, there is bound to be a wide discrepancy in the types of TRIPS-plus provisions that have been negotiated. And considering the wide scope of TRIPS, such provisions are not always directly limiting the use of flexibilities built into TRIPS.

However, in some cases TRIPS-plus provisions have been very restrictive. The most common examples of highly restrictive TRIPS-plus provisions include patent durations beyond the 20-year minimum established in TRIPS Article 33, increased patent protection, and limits on the use of compulsory licenses and parallel imports. Two notable African examples are Kenya and Uganda, both of which have implemented laws that further restrict the use of compulsory licensing and parallel imports. In the case of Uganda, this is despite it being classified as one of the LDCs, and thus eligible for a 10-year extension to the transition period to TRIPS. Another notable example of restrictive TRIPS-plus provisions is the United States' African Growth and Opportunity Act (AGOA). The program provides products originating from countries in Sub-Saharan Africa with duty- and quota-free access to the U.S. market in exchange for, among other things, heightened IPR protection (Cohen-Kohler, Forman & Lipkus, 2008: 241-242).

3 The Patent Dilemma: Restricting Access to Encourage R&D

Throughout the debate surrounding TRIPS, two contrasting notions have been repeatedly brought up. On one hand, concerns over patent protection restricting access to essential medicine have been voiced, whereas on the other hand, the pharmaceutical industry has maintained that the exclusivity granted by patents enables them to recoup their R&D expenditure, and removing such exclusivity would lead to less pharmaceutical R&D. Both points are understandable. However, essential medicine is a very delicate issue, and lack of access can be measured in loss of lives.

Thus, this section begins with an overview of two prominent trade disputes that have shaped the debate on access to medicine. After establishing the context with these disputes, a comparative analysis between the notions of patents restricting access to essential medicine and the necessity of patent protection to encourage R&D will be made in an effort to arrive at a solution that would both facilitate easier access without sacrificing future R&D efforts.

3.1 Prominent Trade Disputes Following the TRIPS Agreement

Criticism, debate and even confusion ensued in the wake of the TRIPS Agreement. The Agreement was criticised for being a "one-size-fits-all" approach to IPR protection that simply extended the IPR laws of developed countries into developing countries (MSF, 2011). Two prominent disputes took place around the turn of the millennium: a joint lawsuit by multinational pharmaceutical companies against the government of South Africa, and a trade dispute between the United States and Brazil. These two widely publicised events brought up important issues with the implementation of TRIPS that needed to be addressed ('t Hoen, 2002: 30-33).

In the mid-1990's, the government of South Africa set to reform their healthcare system. At the time, the country had a two-tiered healthcare system with approximately 20 percent of the population covered by private healthcare, and the remaining 80 percent relying on a highly dysfunctional public sector that suffered from poor administration and infrastructure, as well as corruption and misallocation of resources. At the same time, the country faced an unprecedented increase in HIV infections with the

overall adult prevalence rate nearing the 20 percent mark. As the government was working with a severely limited budget and could thus not afford the costly patented drugs, it sought to address the issue through the use of generic versions of off-patent drugs and a legal amendment that allowed for parallel imports of patented drugs (Fisher & Rigamonti, 2005: 2-4).

In February 1998, the Pharmaceutical Manufacturers Association of South Africa (PMA) filed a suit against the government of South Africa in the High Court of South Africa. The PMA sought to challenge the constitutionality of the new legal amendment as well as its compliance with TRIPS. Already during the media battle that preceded the lawsuit, the PMA had been backed by both the Pharmaceutical Research and Manufacturers of America (PhRMA) – a trade group representing the U.S. pharmaceutical industry – and the United States government. The group of supporters was also joined by the European Commission, which took the stance that the legal amendment both violated TRIPS, and negatively affected the interests of the European pharmaceutical industry (Fisher & Rigamonti, 2005: 3-10). As the matter went to court and the government of South Africa maintained that their actions were both constitutional and TRIPS-compliant, the United States began to withhold trade benefits and threaten with further trade sanctions ('t Hoen, 2002: 30-31).

Despite taking sides with the PhRMA and PMA, the United States did not take the dispute to the WTO Dispute Settlement Body. Over the course of 1999, the dispute gained a great deal of media coverage and consequent public pressure, which arguably persuaded the United States to reconsider their stance. The US Vice President Al Gore, who was also acting as the co-chairman of the United States-South Africa Binational Commission, proved to be an ample target for activists and protestors. He had been active in pressuring South Africa to give in, but ran the risk of having the negative publicity harm his efforts for the Presidential campaign of 2000. In September 1999, the United States announced a shift in their foreign trade policy and withdrew their support from the PMA. The United States and South Africa reached an agreement with the US withdrawing their sanctions, and South Africa pledging to comply with TRIPS. Shortly thereafter, the PMA suspended their lawsuit, and dropped the case unconditionally in April 2001 ('t Hoen, 2002: 31; Fisher & Rigamonti, 2005: 3-10).

Another prominent case at the time was the WTO trade dispute between the United States and Brazil in 2000 (WTO, 2010). Brazil had a successful AIDS program that took advantage of both their capability to manufacture generic drugs locally, as well as the flexibilities built into TRIPS. Local pharmaceutical companies were manufacturing a major share of the drugs needed, and the rest were obtained through negotiations with drug companies. Brazil was actively leveraging their status as a significant buyer and the threat of issuing compulsory licenses in their negotiations to reduce the price of drugs. Through the use of these two tactics, Brazil had managed to reduce the price of antiretroviral drugs by roughly 80 percent (Cohen-Kohler, Forman & Lipkus, 2008: 247).

The Brazilian intellectual property law required the holders of Brazilian patents to manufacture the products in question within Brazil in order to retain patent protection. The patent holders had three years to comply with the requirement, after which the product in question would become subject to compulsory licensing. And in case the patent holder was to simply keep importing the product, parallel imports of third parties would be allowed as well ('t Hoen, 2002: 42).

In May 2000, the United States filed a complaint with the WTO Dispute Settlement Body, claiming that U.S. patent holders were being discriminated and that their rights were being violated. At the core of the complaint was that the Brazilian violated TRIPS Articles 27(1) and 28(1) (WTO, 2010). Article 27(1) stated that a patent should be available for any invention in any field of technology, regardless of whether or not the product was produced locally or imported. Furthermore, Article 28(1) stated that the patent should exclude third parties from making, using, selling or importing the product for the purpose of selling without the consent of the patent owner (WTO, 1994). Brazil, in turn, argued that their actions were consistent with Article 5(A)(4) of the Paris Convention, which is incorporated into TRIPS under Article 2(1) ('t Hoen, 2002: 45). Article 5(A)(4) of the Paris Convention allows for a compulsory license to be issued upon failure to work the patent within three years of the granting of the patent (WIPO, n.d.). Essentially, both governments had a valid point in the argument, but the United States' action was met with fierce criticism.

Brazil had long taken an active role in the debate on access to medicine, and had fully embraced the flexibilities of TRIPS. On numerous occasions, Brazil had also offered their assistance to developing countries in increasing their manufacturing capacity through skills- and technology transfer. Their active participation in the access debate, as well as their status as a model of success, was at least part of the reason why the United States' action was met with such criticism. It was feared that the dispute would negatively affect the Brazilian program, and that it would deter other developing countries from exercising their rights within TRIPS ('t Hoen, 2002: 45).

These two disputes are prominent and telling examples of numerous issues with the TRIPS Agreement. Some member states either lacked full awareness of the flexibilities provided by the agreement, or did not prioritise public health over IPR protection. These disputes also provided a plausible argument for how strict patent protection could affect public health through increasing barriers for access to essential medicine – whether through adding hurdles or simply deterring others from exercising their rights. Lastly, the two disputes also showed warning signs of how the use of political power and coercion was not out of question when it came to protecting influential industries. With this in mind, it is worth asking to which extent TRIPS affects access to medicine.

3.2 Do Patents Restrict Access?

The concern regarding the access gap in developing countries and LDCs has underpinned much of the public debate around TRIPS and its application to pharmaceutical products. The inherent premise with TRIPS is that limitations on the use of new inventions are set in the forms of IPR protection and the exclusivity granted by patents. The possible negative effects of these limitations on public health are then, at least to a certain extent, mitigated by the flexibilities provided in the form of compulsory licensing and parallel imports.

Perhaps the most fundamental criticism of TRIPS has been that it is too wide in scope and does little to differentiate between industries or patentable inventions. TRIPS indeed does very little to differentiate between industries or patentable subject matter. Article 27(1) simply states that patents shall be made available for any inventions – either products or processes – in all fields of technology (WTO, 1994). While it must be acknowledged that the agreement does contain other provisions that enable flexibilities

when, for example, public health is at risk, it is still fair to question whether this is the right approach.

If we consider the fact that a patent grants the patent owner exclusive rights to make and sell their invention at, for example, a price point that maximises their profit, the implications of such behaviour are drastically different depending on the type of product in question. Assuming that a profit maximising price point is out of reach for any number of consumers, the implications are drastically different for a pharmaceutical product when compared to, for example, a memory foam mattress. Not all pharmaceutical products are alike in this regard either. For example, a patent on the foam formulation of a drug against hair loss has arguably much less serious implications than a patent on what is considered to be essential medicine. In the case of essential medicine, the cost of exclusion can be measured in the loss of lives.

Bearing this in mind, it would appear that there is merit in the notion that essential medicine should at least receive special consideration. Thus, it is worth considering to which extent TRIPS affects access to medicine.

3.2.1 Restrictive Effects Attributable to TRIPS

As was already mentioned in section 2.4, TRIPS establishes patent protection on any new invention in any field of technology – including pharmaceutical products – for a minimum duration of 20 years. It is worth noting that patents granted prior to January 1st 1995 were not required to be recognised in the new national laws, meaning that any pharmaceutical product patented prior to that date was free to be manufactured and sold by third parties. The patents granted from January 1st 1995 onwards granted the patent owner the exclusive right to make, sell and import for sale the patented product.

As such, patent protection and the exclusive rights it grants do have effects on drug prices that are generally seen as restricting access. Firstly, the holder of the exclusive rights has the discretion to set the price as they see fit. The estimated average cost of developing a drug is roughly 2.3 billion Euros if accounting for the cost of failures of other drugs (PhRMA, 2015: 2). Considering such a high up-front cost, it is often the case that the price is such that enables the patent owner to recoup the R&D costs as

well as to make a profit. And secondly, the exclusive rights of the patent owner limit the amount of generic competition on the market, which would have a tendency to lead to lower prices. As the manufacturers of generic drugs do not incur the high costs of R&D, they would be able to sell the drug at a much lower price. The case of the Brazilian AIDS program is perhaps one of the most notable examples of the effects of introducing generic competition to the market, having reduced the price of antiretroviral drugs by roughly 80 percent. The effects of drug prices on access to medicine are naturally the most drastic in lower income countries. In regard to the AIDS epidemic in developing countries, it has been estimated that the removal of patent protection on pharmaceutical products, and the consequent effect on drug prices, would increase access to HIV/AIDS therapy by at least 30 percent (Borrell & Watal, 2002: 5).

TRIPS does however, offer flexibilities for cases of public health crises. Article 6 states that the exhaustion of IPR cannot be contested unless it is a question of non-discrimination. This means that each member state is free to determine the point at which IPRs become exhausted. Consequently, it is possible that a product sold in another country at a lower price may be bought there, and imported for sale in another country without the consent of the patent owner, thus facilitating access through a lower drug price. It is up to each member state to determine whether such a practice is allowed, depending on their objectives.

Another key flexibility provided by Article 31 is the use of compulsory licenses, as explained in section 2.4. This enables a member state to issue a license to manufacture a patented product without the consent of the patent owner under various circumstances. In case a voluntary license has not been obtained within reasonable time and under reasonable commercial terms, a non-exclusive compulsory license may be issued. Furthermore, in cases of national emergencies, this requirement may be forgone, and a compulsory license may be awarded promptly. This flexibility aims to mitigate the restrictive effects of patents in cases of public health crises.

The provisions enabling compulsory licensing were amended in 2005, providing further flexibility to LDCs with limited production capacity. As TRIPS Article 31 initially enabled the use of compulsory licensing mainly for domestic markets, the amended Article 31bis took better into account the member states that could not make full use out of

Article 31. Under Article 31bis, developing countries and LDCs which are members of the same regional trade agreement – half of which must comprise of LDCs – and share the same public health concern, may take joint action in compulsory licensing and distributing the products manufactured under a compulsory license to the member states. When using this mechanism, one single member state must handle all administration and distribution on behalf of all member states.

Patent protection does tend to lead to higher drug prices, which in turn may lead to decreased access in poorer countries and among poorer populations. However, it must be noted that TRIPS does at least technically offer two viable alternatives to addressing this access barrier. It must also be noted that most drugs currently classified as essential medicine have already lost their patent protection. However, an increasing number of drugs classified as essential medicine may pose problems in the near future (WHO, 2015).

3.2.2 Potential Further Restriction through TRIPS-Plus Provisions

While TRIPS does offer flexibilities to help combat the negative effects of patent protection on pharmaceutical products, it has been argued that these have been relatively unclear, and that the amendment to the agreement in 2005 added even more hurdles to the flexibilities ('t Hoen, 2002: 41). The varying interpretations and consequent legal battles would at least lend credence to this notion if considered earnestly. Furthermore, it is interesting to note that there were only 24 reported cases of compulsory licensing between January 1995 when TRIPS entered into force, and June 2011. The episodes took place in 17 member states, mostly in upper middle income countries. It is also worth noting that very few episodes took place in LDCs, and even fewer after the amendment of the agreement in 2005 (Beall & Kuhn, 2012).

It is difficult to pinpoint the exact reasons for this surprising lack of compulsory licensing. One reason behind the lack of LDCs using the flexibilities could very well be the lack of resources and legal expertise in order to manoeuvre through the red tape. The study by Beall and Kuhn (2012) also notes that most LDCs had already implemented TRIPS-compliant patent laws well before their deadline by 2004. The fact that the LDCs

had acted much quicker than necessary in ensuring TRIPS-compliance brings to mind the possibility of external pressure from other member states.

If there were concerns over the TRIPS agreement extending western standards of IPR protection to developing countries, perhaps the politics related to international trade and the use of TRIPS-Plus provisions should be the real reason for concern. The two notable disputes discussed earlier revolved around TRIPS, and the case of PMA vs. the South African government showed that the use of political power or coercion is not out of question. As already briefly mentioned, the United States government lent its support to an interest group representing the U.S. pharmaceutical industry by taking a methodical approach to pressuring the government of South Africa. The United States initially placed South Africa on their Special 301 Watch List, which is simply used to identify trade barriers in the form of lacking IPR. Later on, trade benefits for South African products under the Generalized System of Preferences (GSP) program were withdrawn. And finally, United States' development assistance to South Africa was made conditional upon the resolution of the dispute (Fisher & Rigamonti, 2005: 7-8). The European Commission took a more moderate stance with the Vice-President of the European Commission sending a letter to the Vice President of South Africa. The letter urged the South African government to reconsider their stance, and stressed that compulsory licensing would negatively affect the interests of the European pharmaceutical industry ('t Hoen, 2002: 31).

The dispute also provided fascinating insight into the opinions of the parties involved. The United States Ambassador to South Africa stated that "my Government opposes the notion of parallel imports of patented products anywhere in the world" (Fisher & Rigamonti, 2005: 7). The letter sent by the Vice-President of the European Commission also hinted at the possible lobbying power of the European pharmaceutical industry.

The concerns related to political pressure and TRIPS-plus provisions has several moving parts. As TRIPS only sets the minimum standards for IPR, nothing is stopping member states from applying measures stricter than required. As already briefly mentioned in section 2.6, the most concerning TRIPS-plus provisions related to access to medicine are mainly patent durations over the minimum 20 years, and provisions that might block or inhibit the use of compulsory licensing and parallel imports. Another

concern might be exclusivity of test data, which would mean that the producer of generic drugs would not be allowed to use the test data used for the initial patent application. This could seriously slow down the introduction of generic drugs.

It is a legitimate concern that for example LDCs might be pressured or persuaded into adopting TRIPS-plus provisions in exchange for trade benefits. However, should a member state wish to accept such terms, it should be up to them to decide whether the benefits are worth it. For example, a correlation has been shown between stricter IPR laws and foreign direct investment (FDI) decisions related to R&D and patent-centric industries (UNCTAD, 2002: 22). Thus, assuming the country in question was not dealing with public health crises, adopting TRIPS-plus measures in an effort to attract FDI would at least seem somewhat rational. However, it should be noted that there are other, albeit financially costlier, viable options to attract FDI as well. For example, improving the local infrastructure, lowering corporate taxes and paying subsidies could be seen as viable options. The problem in addressing this risk is that member states are free to set their own patent legislation. It is absolutely true that states with high bargaining power might "misuse" IPR to drive their agenda, but so might the states trading away their rights to the flexibilities of TRIPS.

While the possible TRIPS-Plus provisions that would further restrict access to essential medicine are not the fault of TRIPS *per se*, they are a legitimate concern going forward and should thus be noted.

3.3 The Need for Patents to Encourage R&D

Considering the concerns discussed in the previous sections, it would be logical to raise the question of whether patents are necessary. The WTO has understandably argued that TRIPS and IPR protection promote invention, innovation and research (WTO, 2014b). A similar sentiment has been echoed by both pharmaceutical company representatives and interest groups ('t Hoen, 2002: 56; Fisher & Rigamonti, 2005: 5). The general argument is that the exclusive rights granted to the patent owner act as an incentive to conduct research, and provides an opportunity to recoup the R&D expenditure. Consequently, the opposition of compulsory licensing has rested on the notion

that it removes the exclusive rights from the patent owner, and thus reduces the amount of future R&D, as it is not feasible.

However, there is evidence suggesting the contrary. The study by Lerner (2009) measured the effects of patent policy changes on innovation, and found no positive effects. Another study by Qian (2007) had relatively similar results, albeit in more detail, concluding that patent protection alone does not stimulate domestic innovation. The study suggested that the effect of patent protection on innovation is largely dependent the levels of development, education and economic freedom, pointing out that mainly the developed countries showed a positive correlation. Thus, while IPR protection might promote innovation in principle, in reality it is determined by much more than mere patent protection, and simply increasing the level of IPR protection will be unlikely to lead to positive results in less developed countries.

Assessing trends in industry life cycles would also suggest a lack of correlation between patents and innovation; regardless of the initial level of patent protection, it mostly plays a key role only after the innovative activity has peaked. The concept of industry life cycle as presented by Porter (1980: 156-188) has been around for decades, and it is still widely regarded as the cornerstone of life cycle analyses.

Typically, the industry is relatively fragmented in the early stages, meaning that there are several firms each with relatively little control of the direction of the industry. As the market is relatively undeveloped, there tends to be a high amount of product differentiation, as each new entrant is trying to understand and answer customer needs, and to get their product on the market. The competition in the earliest stages is focused mostly on gaining first-mover advantages. As the industry matures, it tends to consolidate through mergers, acquisitions and exits of firms, and consequently the influence of individual firms is increased. And as the market becomes more developed, the differentiation of products will reduce over time, and the products will be mass produced. At some point of the life cycle, growth will inevitably level, and the competition will turn to focus more on market share between the existing firms. At this stage, the nature of competition will also change, as there will be less innovation in the industry. It could be argued that at this stage, the competitive means change from offensive

ones – e.g. innovation and differentiation – to more defensive ones, such as the use of IPR to inhibit competitors and new entrants.

The recent boom of the smart phone and tablet industry would be an appropriate example of this, down to the emergence of the heavy use of patent litigation as a measure to inhibit competitors. The widely publicised, so-called smart phone patent wars, arguably truly escalated well after the initial burst of innovation. Various national pharmaceutical industries have followed a similar life cycle, beginning with a spur of innovation in the absence of patent protection, and only having it introduced after the industry had matured. For example, product patents for pharmaceuticals were introduced in Germany in 1967, Switzerland in 1977, and France and Italy in 1978 (Condon & Sinha, 2008: 171). The study by Qian (2007: 450) also postulates that a phenomenon similar to the life cycle hypothesis presented earlier is taking place at a national level. The study notes that countries tend to oppose patent laws when they are technology importers, and only begin to show an interest in stronger IPR when they have become technology exporters.

Another argument against patents was already hinted in the example of them being used as a competitive measure to inhibit competitors and new entrants. That is that they have the potential to hinder innovation and slow down the diffusion of information. The smart phone patent wars have provided an excellent example of what could be considered a negative externality: patent trolling. In 2011, Google acquired Motorola Mobility and their portfolio of 17,000 patents for US$12.5 billion. The main motivation for the purchase has been widely considered to be a patents arms race with other smart phone manufacturers, as the patents provide an opportunity to sue, counter-sue and "tax" competitors (WSJ, 2011). This kind of activity has two potential negative effects: firstly, it may hinder the innovation of others, and secondly, it may lead to higher consumer prices due to licensing fees having to be paid by the competitors infringing the patents.

If patent protection appears to have little influence on innovation, it would then be reasonable to consider what would happen to the development of essential medicine in its absence. In regard to pharmaceutical products, the chemical compounds used are most often already known, but the efficacy is the most crucial aspect of the product.

Most of the R&D expenditure is spent on establishing the efficacy, and actually producing the product is relatively inexpensive. Furthermore, the lengthy pre-market trials are argued to last an average of 10 years, meaning that once the product is on the market, there is only half of the patent duration left to enjoy the exclusive rights granted by the patent (PhRMA, 2015: 37).

The pharmaceutical industry is unique in this regard that the R&D costs are extremely high, and that the lengthy trials eat away half of the patent duration prior to the product entering the market. This sentiment was echoed in a statement by a representative of Bristol-Myers Squibb, a pharmaceutical manufacturer, in the statement that: "Patents are the lifeblood of our industry. Compulsory licensing and parallel imports expropriate our patent rights," further adding that the only beneficiary of these activities is the generic drug industry (Fisher & Rigamonti, 2005: 5). The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has also shared this sentiment, stating that compulsory licensing is a threat to public health by denying future benefits of the R&D capabilities of the research-based pharmaceutical industry ('t Hoen, 2002: 56).

Considering the key role of pharmaceutical products in public health, and the high cost of exclusion associated with patent protection on essential medicine, this raises the question of whether the development of essential medicine should rest in the hands of commercial pharmaceutical companies to begin with. And considering that these companies are also responsible to their shareholders, it is safe to assume that their motivation is not necessarily to promote public health, but rather to be profitable and increase shareholder wealth. This is especially problematic in the case of developing countries and their need for affordable essential medicine. It might simply not be feasible to incur the high costs of developing a drug that is tailored for markets that are not able to pay prices that would allow the manufacturer to recoup their R&D expenditure. If the decisions on which drugs to develop are made on the basis of profitability, it might very well be that developing a drug to combat, for example, erectile dysfunction or hair loss is a much more lucrative project than a drug that is not needed in developed countries.

This notion of certain types of drugs being more profitable, and thus more lucrative projects for R&D investment is also shown in the types of drugs being developed by commercial pharmaceutical companies. Approximately one percent of new chemical entities marketed between 1975 and 1999 were for tropical diseases and tuberculosis. Furthermore, only 0.2 percent of the global R&D expenditure went to pneumonia, diarrhoeal diseases and tuberculosis despite them representing 18 percent of the global disease burden at the end of the 1990's. And lastly, in the early 2000's it was reported that 98 percent of the revenue for HIV/AIDS-related medicine came from OECD countries. The subtype of the virus most common in this area is not the one most common globally, and does not represent the largest burden of disease (Condon & Sinha, 2008: 172-174). The WHO calls this the "10/90 gap", meaning that only 10 percent of the global spending on research is devoted to diseases that represent 90 percent of the global disease burden (WHO, 2016c). In this light, and considering the comments of the representatives of the commercial pharmaceutical industry, the removal of patent protection for essential medicine would presumably only lead to a slight drop in R&D expenditure for essential medicine.

It might then be reasonable to raise the question of who exactly is funding pharmaceutical R&D. It has proven relatively difficult to obtain exact figures on how the spending on pharmaceutical R&D is divided between the public and private sectors. Further complications might arise due to accounting, as in some countries the state might for example provide tax credits on R&D, essentially meaning that they incur part of the cost indirectly. However, most statistics that could be found suggest that public spending on pharmaceutical R&D represents roughly between 40 and 60 percent of the total (PhRMA, n.d.; WHO, 2004: 13; Boldrin & Levine, 2008: 256-257).

Scientific institutes such as universities and hospitals as well as specific research institutes tend to represent a major proportion of public pharmaceutical research. Within the last 30 years, especially universities have become a valuable source of drug discovery. Due to the tendency of such institutes to promote the advancement of science, it would be reasonable to assume that their inclination is, at least to a certain extent, geared more towards public health. The areas of focus for the Academic Drug Discovery Consortium – a major network of drug discovery centres including several universi-

ties – would support this notion, as their largest areas of focus include oncology, infectious diseases and immunology (ADDC, 2012).

As regards the relationship between patent protection and pharmaceutical research in scientific institutes, there is much less data available than in the case of commercial pharmaceutical companies. However, it must be noted that within the last 30 years, universities have become increasingly involved in the pharmaceutical industry through patent ownership and licensing agreements with commercial pharmaceutical companies. It is, however, difficult to establish to which extent their research is focused on making patentable and licensable discoveries. Considering that commercial pharmaceutical companies are the most vocal proponents of patent protection and the fact that the funding structure is drastically different in the public sector, it would make sense that relationship between patent protection and R&D efforts would differ as well. The fact that extremely few of the patents held by universities are financially significant would lend further credence to this notion (Edwards, Murray & Yu, 2003: 618).

3.4 Suggestions

One possible, perhaps radical, way to address the access problem that should be explored is the removal of patent protection for essential medicine. This would provide immediate relief to the access problem for the drugs that already exist through the removal of any IPR barriers to access. Such a measure has been, for example, postulated to increase access to HIV/AIDS therapy by at least 30 percent (Borrell & Watal, 2002: 5). Furthermore, it would not likely lead to a significant drop in R&D for essential medicine, as it tends to receive very little attention from commercial pharmaceutical companies to begin with. However, as the R&D would likely mostly rely on public funding, significant research should be done on the effects of patent protection on publicly funded R&D before this could be considered as a viable option.

The removal of patent protection, while perhaps a radical notion, would not be an entirely new concept. Trade barriers have been removed in the past to make way for free trade, so a similar treatment to patent protection should not be an alien concept. Furthermore, this transition could be done through gradual shortening of patent duration,

for example. Until the feasibility of the aforementioned notion is thoroughly examined, we are left to rely on the commercial sector and TRIPS system to a certain extent.

TRIPS in itself does present barriers to access to medicine simply by establishing patent protection and granting exclusive rights to patent holders. The lack of generic substitutes has been linked with higher drug prices, and the minimum patent duration of 20 years significantly delays the introduction of generic competition that would lower the prices. While the agreement does provide flexibilities to aid member states dealing with public health crises, the mechanisms appear to be relatively complicated, and the use of such flexibilities has been few and far between. Exporting to LDCs under a compulsory license would be much more straight-forward without the requirement of both countries being within the same FTA, of which at least half of the members are LDCs. For example, allowing for exports of necessary quantities of drugs to a LDC within the same continent would ease access while protecting the commercial interests of the patent holder to a reasonable extent.

While certain governments and the pharmaceutical industry have not received the most favourable presentation in this paper, it must be pointed out that they do have initiatives in place to address the access problem. For example, Novartis has a non-profit partnership in place with the Singapore Economic Development Board, in order to provide a cure for dengue, malaria and tuberculosis (Novartis, 2014). Such charitable initiatives are many, albeit fragmented, which could be seen as leading to a limited impact.

There are also other initiatives much larger in scale, such as the United States President's Emergency Plan for Aids Relief (PEPFAR) and the United Nations' UNAIDS. While these initiatives have come under criticism for lack of focus and coordination, both the United States and United Nations have ties to various other programs. Perhaps one of the most comprehensive and focused programs is the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund). As the name implies, the program focuses on a wider range of diseases and works to both prevent and treat the diseases (The Global Fund, 2014). Considering the approach, scope and magnitude of the program, and seeing that education and prevention are also crucial areas in preventing AIDS, this could be considered to have high potential.

The Medicines Patent Pool (MPP) is another promising program. The MPP is financed by UNITAID, which in turn comprises of 28 member states and the Bill & Melinda Gates Foundation, and acts as a mediator between the patent holders and generic manufacturers. The aim of the program is to negotiate voluntary licenses for essential medicine, which are in turn sublicensed to manufacturers of generic drugs (MPP, n.d.). Such a mechanism could be a viable option in expediting the market entry of generic versions of patented drugs, consequently lowering the prices in general. While the mechanism is based on voluntary licensing of existing drugs at the moment, it could also work as an incentive to develop drugs that cater to a market that would otherwise seem unprofitable.

It would seem feasible to coordinate such efforts, eliminating overlapping agendas, and focusing increased efforts on the programs that show the most promise. While certainly a monumental task, an organization such as the WHO could be used to consolidate the efforts of the member states. An approach such as this would arguably be a band aid solution, as it essentially manipulates the system – i.e. TRIPS – to work towards promoting public health, but in the absence of fundamental adjustments to it, it might be the only way to work towards a solution both in the short and long term.

4 Conclusion

Essential medicine deserves special recognition in terms of IPR. It plays a central role in the access problem and public health in general. Furthermore, the social costs of exclusion in terms of welfare losses are unique and most severe for this group of products. The occasionally heated public debate surrounding the access problem further validates this point.

The TRIPS agreement has, to a certain extent, created barriers to access in the short term, and is unlikely to substantially promote neither innovation in essential medicine nor the development of innovative capacities in developing countries and LDCs in the long term. In the short term, and in regard to access to essential medicine, TRIPS has added barriers simply by subjecting essential medicine to patent protection, which in turn has been linked with decreased competition and higher drug prices. While the agreement has provided flexibilities in the form of compulsory licensing and parallel imports, these mechanisms have complicated the process of accessing affordable essential medicine and could be simplified to improve access while maintaining the legitimate interests of the patent owner. In the long run, there are likely to be very few positive effects on the development of innovative capacities in developing countries attributable to TRIPS. While it is understandable that, at least in principle, patent protection and the exclusive rights it grants provide an incentive for inventors, it has been shown that the development of innovative capacities is much more dependent on the levels of economic development, education and economic freedom than the level of patent protection. Furthermore, by imposing limitations on generic drug manufacturing, it is arguable that TRIPS will hinder the diffusion of information and build-up of knowledge and innovative capacities in countries such as India and Brazil, which are known as major producers of generic drugs.

TRIPS is also unlikely to solve the fundamental problem underpinning the access problem. Even if the agreement did promote innovation, it would be extremely unlikely to promote innovation from commercial pharmaceutical companies related to curing diseases that are not profitable. Thus, we should not rely on commercial ways to address the access problem, but rather turn towards the public sector. Charitable efforts such as patent pooling might be one possible band aid solution to making R&D on neglected

diseases more worthwhile for the commercial pharmaceutical companies. Under this system, the mediators would make licensing agreements with patent owners, and essentially pay on behalf of those who cannot afford essential medicine.

Further studies should be done on the effects of patent protection on R&D in the public sector in order to assess whether removing patent protection from essential medicine would be feasible. Removing such protection would ease access in the short term, but the question that remains is whether such a measure would entail a drop in public sector R&D towards essential medicine in the long term. Finally, even if this measure were to be pursued, the R&D efforts towards neglected diseases should be scaled up through public funding, and coordinated by a body with enough legal power, such as the WHO.

References

Academic Drug Discovery Consortium, 2012. *Projects Statistics.* [online] Available at: <http://www.addconsortium.org/projects_statistics.php> [Accessed 5 April 2016]

Barton, J.H., 2004. TRIPS and The Global Pharmaceutical Market. *Health affairs*, vol. 23, no. 3, pp. 146-54.

Beall, R., Kuhn, R., 2012. Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis. *PLoS Medicine*, [e-journal] 9(1). Available at: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154> [Accessed 5 April 2016]

Boldrin, M., and Levine, D. *Against Intellectual Monopoly*. New York: Cambridge University Press, 2008.

Borrell, J-R. and Watal, J., 2002. *Impact of Patents on Access to HIV/AIDS Drugs in Developing Countries.* [online] Available at: <http://www.hks.harvard.edu/content/download/69212/1249658/version/1/file/092.pdf> [Accessed 5 April 2016]

CIA World Factbook, no date. *Africa*. [online] Available at: <https://www.cia.gov/library/publications/the-world-factbook/wfbExt/region_afr.html> [Accessed 5 April 2016]

Cohen-Kohler, J., Forman, L. and Lipkus, N., 2008. Addressing legal and political barriers to global pharmaceutical access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards. *Health Economics, Policy and Law*, vol. 3, no. 3, pp. 229-56.

Condon, B.J. and Sinha, T. *Global Lessons from the AIDS Pandemic: Economic, Financial, Legal and Political Implications.* Heidelberg: Springer-Verlag, 2008.

Edwards, M., Murray, F. and Yu, R., 2003. Value creation and sharing among universities, biotechnology and pharma. *Nature Biotechnology,* Vol. 21, No. 6, pp. 618-624.

European Patent Office, 2013. *The European Patent Convention.* [online] Available at: <http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461C0D5C1257C060050C376/$File/EPC_15th_edition_2013.pdf> [Accessed 5 April 2016]

Fisher, W., Rigamonti, C., 2005. *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*. [online] Available at: <http://cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf> [Accessed 5 April 2016]

Medicines Patent Pool, no date. *About the MPP*. [online] Available at: <http://www.medicinespatentpool.org/about/> [Accessed 5 April 2016]

Médicins Sans Frontières, 2011. *TRIPS, TRIPS Plus and Doha*. [online] Available at:

<http://www.msfaccess.org/content/trips-trips-plus-and-doha> [Accessed 5 April 2016]

Novartis, 2014. *Novartis Institute for Tropical Diseases (NITD)*. [online] Available at: < https://www.nibr.com/our-research/institutes/novartis-institute-tropical-diseases> [Accessed 5 April 2016]

't Hoen, E., 2002. TRIPS, pharmaceutical patents, and access to essential medicines: A long way from Seattle to Doha. *Chicago Journal of International Law*, vol. 3, no. 1, pp. 27-46.

Pharmaceutical Research and Manufacturers of America, 2015. *2015 Profile.* [online] Available at: <http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf> [Accessed 5 April 2016]

Pharmaceutical Research and Manufacturers of America, no date. *R&D Spending.* [online] Available at: <http://www.phrma.org/private-public-rd-spending> [Accessed 5 April 2016]

Porter, M. E. *Competitive Strategy: Techniques for Analyzing Industries and Competitors*. New York: Free Press, 1980.

The Global Fund, 2014. *About the Global Fund*. [online] Available at: <http://www.theglobalfund.org/en/impact/> [Accessed 5 April 2016]

The Wall Street Journal, 2011. *Google, Motorola and the Patent Wars*. [online] Available at: <http://www.wsj.com/articles/SB10001424053111903639404576518493092643006> [Accessed 5 April 2016]

Tufts Center for the Study of Drug Development, 2014. *Cost of Developing a New Drug.* [online] Available at: <http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf> [Accessed 5 April 2016]

UNAIDS, 2013. *Core Epidemiology Slides*. [online] Available at: <http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/201309_epi_core_en.pdf> [Accessed 5 April 2016]

UNAIDS, 2015. AIDS by the numbers 2015. [online] Available at: <http://www.unaids.org/sites/default/files/media_asset/AIDS_by_the_numbers_2015_en.pdf> [Accessed 5 April 2016]

United Nations Conference on Trade and Development, 1997. *The TRIPS Agreement and Developing Countries*. [online] Available at: <http://unctad.org/en/docs/ite1_en.pdf> [Accessed 5 April 2016]

United States Patent and Trademark Office, 2016. *Patent Laws, Consolidated.* [online] Available at: <http://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf> [Accessed 5 April 2016]

World Health Organization, 2004. *The World Medicines Situation.* [online] Available at:

<http://apps.who.int/medicinedocs/pdf/s6160e/s6160e.pdf> [Accessed 5 April 2016]

World Health Organization, 2015. *Tough Decisions on Essential Medicines in 2015.* [online] Available at: <http://www.who.int/bulletin/volumes/93/4/15-154385/en/> [Accessed 1 May 2016]

World Health Organization, 2016a. *Tuberculosis.* [online] Available at: <http://www.who.int/mediacentre/factsheets/fs104/en/> [Accessed 5 April 2016]

World Health Organization, 2016b. *Malaria.* [online] Available at: <http://www.who.int/mediacentre/factsheets/fs094/en/> [Accessed 5 April 2016]

World Health Organization, 2016c. *Research and Development.* [online] Available at: <http://www.who.int/trade/glossary/story079/en/> [Accessed 5 April 2016]

World Health Organization, 2016d. *Essential Medicines and Health Products.* [online] Available at: <http://www.who.int/medicines/services/essmedicines_def/en/> [Accessed 1 May 2016]

World Intellectual Property Organization, no date. *Frequently Asked Questions*. [online] Available at: <http://www.wipo.int/patents/en/faq_patents.html> [Accessed 5 April 2016]

World Intellectual Property Organization, no date. *Paris Convention for the Protection of Industrial Property.* [online] Available at: <http://www.wipo.int/treaties/en/text.jsp?file_id=288514> [Accessed 5 April 2016]

World Trade Organization, 1994. *Agreement on Trade-Related Aspects of Intellectual Property Rights*. [online] Available at: <http://www.wto.org/english/docs_e/legal_e/27-trips.pdf> [Accessed 5 April 2016]

World Trade Organization, 2001. *Declaration on the TRIPS Agreement and Public Health*. [online] Available at: <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> [Accessed 5 April 2016]

World Trade Organization, 2003. *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. [online] Available at: <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> [Accessed 5 April 2016]

World Trade Organization, 2010. *Dispute DS199: Brazil - Measures Affecting Patent Protection*. [online] Available at: <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm> [Accessed 5 April 2016]

World Trade Organization, 2014a. *The Uruguay Round*. [online] Available at: <http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm> [Accessed 5 April 2016]

World Trade Organization, 2014b. *Intellectual Property: Protection and Enforcement*. [online] Available at: <http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm> [Accessed 5 April 2016]

World Trade Organization, 2014c. *Glossary*. [online] Available at: <http://www.wto.org/english/thewto_e/glossary_e/glossary_e.htm> [Accessed 5 April 2016]

World Trade Organization, 2016. *Least-developed countries.* [online] Available at: <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm> [Accessed 5 April 2016]

Excerpts from the TRIPS Agreement

PART I

GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

PART II

STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[5] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

[5] For the purposes of this Article, the term "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[6] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

[6] This right, like all other rights conferred under this Agreement in respect to the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[7] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably

practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(d) such use shall be non-exclusive;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

[7] "Other use" refers to use other than that allowed under Article 30

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[8]

[8] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

PART VI

TRANSITIONAL ARRANGEMENTS

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least developed country Member, accord extensions of this period.